Microbiology Expert Committee (MEC) Meeting Summary

September 13, 2022

1. Roll Call:

Cody, Chair, called the meeting to order at 1:30pm Eastern on September 13, 2022 by teleconference. Attendance is recorded in Attachment A – there were 8 voting members present. Associates present: Nigel Allison, Tiffany Carey

The agenda is amended to include SIRs that have been returned.

2. Training Course in Crystal City, VA – Summer Meeting

Training went well in Virginia. There was good participant involvement. The webinars will begin in a few months. There will be one a month to complete the series.

The attendees would like to still receive a handout for the class they took. Paul Junio has the attendance list. They also did not get a quiz.

3. SIRs 423 and 425

SIR 423 and SIR 425 have been returned for reconsideration.

LASEC would like to see the last sentence removed from both responses. The Standard should not refer to variations among ABs.

"Therefore, each laboratory location must perform these checks." was added to SIR 425.

SIR 423

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M5
Section (eg. C.4.1.7.4)	1.7.3.6.d

Describe the problem:

In a recently published SIR of V1M5: 1.7.3.b.i, the interpretation allows the media performance testing language of "at a minimum with first use" to be applied by the laboratory as "before first use, or with the first used". V1M5: 1.7.3.6.d states that each batch of ready-to-use lot of medium and each batch of medium prepared in the laboratory shall be tested with at least one or more known negative and positive culture control 'prior to first use of the medium".

These sections do not specify that the culture controls must be performed "by the laboratory" (as stated in V1M5: 1.7.3.1.a for sterility checks), nor do they specify "the laboratory shall perform" the

culture controls on media (as stated in V1M5: 1.7.3.1.a.i for sterility checks). V1M5: 1.7.3.6.d states that the media must be tested with known positive and negative culture controls prior to first use, but not why whom.

Are positive and negative culture controls that have been performed by the media manufacturer for pre-prepared, ready-to-use medium or medium prepared in the laboratory, or both acceptable to meet this TNI requirement?

Committee Comment:

Response: The language in V1M5 1.7.3.6.d of the 2016 TNI Standard does not prohibit the use of positive and negative culture controls performed by the manufacturer, however the laboratory must prove that the testing meets the requirements of Section 1.7.3.6.d.i.b and 1.7.3.6.d.ii.b . These Sections of the Standard do explicitly state that lab-prepared media shall be analyzed with control cultures. Refer to the program, client, and AB requirements as appropriate for acceptance guidelines.

SIR 425

Standard	2016 TNI Standard
Volume and Module (eg. V1M2)	V1M5
Section (eg. C.4.1.7.4)	V1M5, Section 1.7.3.1.b.i

Describe the problem:

A previous SIR dated 12/11/19 clarified the requirement for sterility checks to be performed by each location using the materials. "The laboratory location using the materials is responsible for performing the sterility check. Using the example provided, each sister laboratory is required to perform their own sterility check. A sterility check does not need to be performed until the items are received in their final location of use."

Does the same apply for media checks appearing in 1.7.3.1.b.i? In other words must EACH LABORATORY LOCATION using the same lot of media perform the performance checks defined in 1.7.3.1.b.i?

Committee Comment:

Response:

The preamble, Section 1.7.3.1 states "The laboratory shall demonstrate and document that the quality of the reagents and media used is appropriate for the test concerned including, but not limited to, test conditions and incubation times". Therefore, each laboratory location must perform these checks. Program, client and/or AB requirements may dictate that each location to perform these checks.

A motion was made by Amy to resubmit SIR 423 and SIR 425 with the language changes above. The motion was seconded by Matt.

Roll Call Vote:

Cody - For

Matt - For

Amy - For

Robin - For

Jody - For

Elisa - For

Christabel - For

Maria – For

Ashley - For

One more vote is needed for a Super Majority. Cody will send the vote out by email to complete it.

(Addition: Cody sent the vote out for email and the following additional email votes were received:

9/13/22 – Hunter For

The motion passed and the SIRs will be sent back to LASEC.)

4. Comments to Posted DRAFT Standard

DI Water checks

Talked about cutting out the blue language. There appears to be agreement. The red language is the question – laboratory that is in compliance with these standards. Also "certified or accredited laboratory that is in compliance with these standards".

Amy – asked why the blue was taken out.It is covered in other areas – delete it. If you have issues with your water, you will find it. These tests help with troubleshooting, and it doesn't do anything else. There is already so many quality controls.

Amy would like to see this left in for consistency's sake between ABs. Robin asked what additional information this would give. The Standard should be focused on the lab. Robin thinks other parts of the test will show the issues, so this is not necessary. There are other provisions in the standard and the methods that cover this. Dwayne is also concerned about taking it out.

Dwayne said they want people to be certified to do testing. The lab doing internal testing would need to be accredited to do the testing for metals. If they send out the testing, it needs to be sent to a lab that is accredited for the metals in question.

Cody asked if there are any other ABs that would have an issue removing the blue language or keeping the red language. Dwayne and Amy have a problem with it. Dwayne and Amy offered to work on some language to bring back to the next meeting.

Dwayne (Pennsylvania AB) - Conductivity and chlorine do not need to be done by an accredited lab. Doesn't need to be on scope. HPC testing does need to be done correctly and the method will be looked at to make sure it is being done correctly. Started giving accreditation for HPC reagent water only.

The drafted language will be sent to the committee for email comment. This will be sent out within a week of the next meeting.

Cody looked at the analyst verification voted on previously - Comment 5. Cody has some concern about the language. Do they need to do the full corrective action process defined for that laboratory?

The lab defines what taking corrective action means. That is what they need to follow. No need to update.

5. Implementation Guidance

Does this need to still be addressed? Equilibrium – Yes.

Current guidance will stay in place – membrane filtration. Standard won't be out for a while.

6. New Business

None.

7. Next Meeting and Close

The next meeting will be by teleconference on October 11, 2022 at 1:30pm Eastern.

A summary of action items and backburner/reminder items can be found in Attachment B and C.

Cody adjourned the meeting at 2:43 pm Eastern.

Attachment A

Participants Microbiology Expert Committee (MEC)

Members	Affiliation	Balance	Contact Information
Cody Danielson (Chair) (2025) Present - For	Oklahoma	Lab	Cody.Danielson@deq.ok.gov
Matt Graves (2025*) Present - F	ERA	Other	Matt_graves@waters.com
Lily Giles (2025) Absent	Louisiana	AB	Lily.Giles@LA.GOV
Amy Hackman (2025*) Present - F	Indiana	AB	mrobinson@isdh.IN.gov
Robin Cook (Vice Chair) (2024*) Present - F	City of Daytona Beach, EML	Lab	cookr@codb.us
Ashley Larssen (2024*) Present -2pm	KC Water	Lab	ashley.larssen@kcmo.org
Jody Frymire (2025) Present - F	IDEXX	Other	Jody-Frymire@idexx.com
Jessica Hoch (2025) Absent	TCEQ	Other	Jessica.hoch@tceq.texas.gov
Elisa Snyder (2023*) Present – left at 2pm	City of Austin – Austin Water Division	Lab	elisa.snyder@austintexas.gov
Hunter Adams (2023*) Absent	City of Wichita Falls – Water Purification	Lab	hunter.adams@wichitafallstx.gov
Enoma Omoregie (2024) Absent	NYC DOHMH	Lab	eomoregie@health.nyc.gov
Christabel Monteiro (2024) Present - F	Pace National, Analytical	Lab	christabel.monteiro@pacelabs.com
Robert Royce (2025*) Absent	New Jersey	AB	Robert.royce@dep.nj.gov
Maria Friedman (2025*) Present - F	California	AB	qamfriedman@gmail.com
Ilona Taunton (Program Administrator) Present	The NELAC Institute	n/a	Ilona.taunton@nelac-institute.org

Attachment B Action Items – MEC

		WIEC	Exported	Actual
	A T.	***	Expected	
	Action Item	Who	Completion	Completion
104	Implementation Guidance for Equilibrium.	Committee	TBD	See note in
				5/11/21 minutes.
105	Discuss definition of Lot with Chair of CSDP	Kasey	2/11/21	Started, but
	EC.	Paul Junio		ongoing.
				7/13/21: Remove
112	Develop Understanding Microbiology Course	Cody	TBD	7/12/22: Ready
		Committee		for first class in
				VA.
113	Complete Response to Draft Comments	All	Ongoing	5/10/22: Voted
	Process			on Comments:
				2, 3, 7, 8, 9 and
				10
				6/14/22: Voted
				on Comments 5
				and 6.

Attachment C

Backburner / Reminders – MEC

	Item	Meeting Reference	Comments
1	Update charter (if needed) every 5 years.	n/a	Ongoing
2	Review Method codes and send comments to Robin for Dan Hickman.		Moved to back-burner on 6/9/20.
3	Provide an update on what has been done with the method codes and database after Jennifer's review and internal EPA meetings.		This was moved from the Action Items table. Notes: 6/9/20: Ask Jennifer for a follow-up. 11/9/20 – Not available for a follow-up.